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| APPLICATION NO.                                | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------|----------------------|---------------------|------------------|
| 10/517,381                                     | 08/22/2005      | Nobuya Kaneko        | 04208.0210          | 3951             |
| 22852  | 7590 09/11/2006 | EXAMINER             |                     |                  |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER |                 |                      | GAMI, TEJAL         |                  |
| LLP  |                 |                      |                     |                  |
| 901 NEW YORK AVENUE, NW                        |                 |                      | ART UNIT            | PAPER NUMBER     |
| WASHINGTON, DC 20001-4413                      |                 |                      | 2193                |                  |
|  |                 |                      |                     |                  |

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   |  | 5/L  |  |  |  |
|---|---|--|--|--|--|--|
|   |   | Application No.  | Applicant(s)   |  |  |  |
|   |   | 10/517,381   | KANEKO ET AL.  |  |  |  |
|   | Office Action Summary   | Examiner   | Art Unit   |  |  |  |
|   |   | Tejal J. Gami  | 2193   |  |  |  |
| Period fo   | The MAILING DATE of this communication app  | ears on the cover sheet with the o   | correspondence address   |  |  |  |
| A SH<br>WHIC<br>- Exte<br>after<br>- If NC<br>- Failu<br>Any  | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE in a sign of time may be available under the provisions of 37 CFR 1.11 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing end patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirwill apply and will expire SIX (6) MONTHS from . cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |
| Status  |   |  |  |  |  |  |
| 1)⊠   | Responsive to communication(s) filed on 22 A  |  |  |  |  |  |
| 2a)□  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |  |  |  |  |  |
| 3)[   |   |  |  |  |  |  |
|   | closed in accordance with the practice under E  | x parte Quayle, 1935 C.D. 11, 4  | 53 O.G. 213.   |  |  |  |
| Disposit  | ion of Claims   |  |  |  |  |  |
| 4)⊠   | Claim(s) 6 is/are pending in the application.   |  |  |  |  |  |
|   | 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |  |  |  |  |
| 5)□   | 5) Claim(s) is/are allowed.   |  |  |  |  |  |
| •   | ☑ Claim(s) <u>6</u> is/are rejected.  |  |  |  |  |  |
|   | Claim(s) is/are objected to.  |  |  |  |  |  |
| 8)[_]   | Claim(s) are subject to restriction and/o   | r election requirement.  |  |  |  |  |
| Applicat  | ion Papers  |  |  |  |  |  |
| 9)[   | The specification is objected to by the Examine   | er.  |  |  |  |  |
| 10)⊠ The drawing(s) filed on <u>10 December 2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.   |   |  |  |  |  |  |
| . Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).                                  |   |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |  |  |  |  |  |
| Priority  | under 35 U.S.C. § 119   |  |  |  |  |  |
| 12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of:                          |   |  |  |  |  |  |
| 1.⊠ Certified copies of the priority documents have been received.  |   |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |   |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |   |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received. |   |  |  |  |  |  |
| - ;   | See the attached detailed Office action for a list  | of the certified copies not receive  | eu.  |  |  |  |
| Attachme  |   |  | (770.440)  |  |  |  |
|   | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)   | 4) Interview Summar<br>Paper No(s)/Mail I  |  |  |  |  |
| 3) X Info   | ce of Draftsperson's Patent Drawing Review (P10-946)<br>rmation Disclosure Statement(s) (PTO-1449 or PTO/SB/08<br>er No(s)/Mail Date <u>22 Aug 2006, 02 Aug 2005, 11 Feb 200</u>  | ) 5) Notice of Informal  | Patent Application (PTO-152)   |  |  |  |

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## **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvi33.ous at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd et al. (U.S. Pub. No. 2003/0069795) in view of Wang Ho (U.S. Pub No 2003/0093229).

As to independent claim 6, Boyd discloses a medicine prototype support system (Fig. 1) (Applicant's Specification discloses on Page 1, Lines 7-16 a medicine prototype support system and method for a composition formed by ingredients, such as health food, other food, cosmetics, etc. Boyd teaches [0018] a product being a composition that can be manufactured such as medical goods, food, chemicals, etc.) for an ingredient manufacturer (Fig. 1 Raw Material Supplier 20) developing medical product at a request of a product manufacturer (Fig. 1 Product Manufacturer 50) (see [0026] for requesting by issuing a purchase order using a product request form), comprising

a product manufacturer system (e.g. product manufacturer computer system)

(see [0025]) of the product manufacturer (Fig. 1 Product Manufacturer 50), an ingredient

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manufacturer system (Fig. 1 Supplier Data Management System 10) of the ingredient manufacturer (Fig. 1 Raw Material Supplier 20), and a plurality of composition manufacturer systems (e.g. instrumentation or Laboratory Information Management System) (see [0021]) of composition manufacturers (e.g. factories) (see [0020]) which the ingredient manufacturer (Fig. 1 Raw Material Supplier 20) requests to manufacture a composition (see [0020] for batch of raw materials produced in factories and [0022] for a system where the supplier enters properties and information pertaining to a batch of raw material), which are connected through communications means (e.g. network) (see [0022]), wherein

the product manufacturer system (e.g. product manufacturer computer system) (see [0025]) comprises transmission means (e.g. network) (see [0025]) for transmitting at least main ingredient information (see [0022] for supplier to enter properties and other information to be shipped to the product manufacturer) about a medical product to the ingredient manufacturer system (Fig. 1 Supplier Data Management System 10);

the ingredient manufacturer system (Fig. 1 Supplier Data Management System 10) comprises:

a database (Fig. 1 database 68) (see [0040]) comprising confidential (e.g. secure) (see [0028] and [0060]) first main ingredient information and second main ingredient information after information conversion (e.g. generate a certificate of analysis by comparing data with specifications using a database) (see [0028]) corresponding to the first main ingredient information (e.g. the one with a best matching the desired material can be selected) (see [0027]);

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information conversion means (e.g. fingerprinting) (see [0027]) for information conversion from the main ingredient information to second main ingredient information corresponding to the main ingredient information (e.g. the one with a best matching the desired material can be selected) (see [0027]) using the database (Fig. 1 database 26) (e.g. generate a certificate of analysis by comparing data with specifications using a database) (see [0028]) when the main ingredient information is confidential first main ingredient information (e.g. secure access means) (see [0022] and [0060]); and

transmission means (e.g. network) (see [0022]) for transmitting to the plurality of composition manufacturer systems (e.g. instrumentation or Laboratory Information Management System) (see [0021]) second main ingredient information (e.g. the one with a best matching the desired material can be selected) (see [0027]) converted by the information conversion means (e.g. fingerprinting) (see [0027]), wherein

the plurality of composition manufacturer systems (e.g. instrumentation or Laboratory Information Management System) (see [0021]) comprise transmission means (e.g. network) (see [0022]) for transmitting composition manufacture information about the manufacture of a part of a manufacture process (Fig. 1 manufacture 43) (see [0035]) of the medical product (Fig. 1 product 44) (see [0035]) to the ingredient manufacturer system (Fig. 1 Supplier Data Management System 10) (see [0057]-[0059]) for integrated manufacturing system).

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However, Boyd does not mention composition ingredient determination means and means for transmitting the composition ingredient information. Wang Ho teaches

A system (see Wang Ho: Fig. 5 for drug-discovery pipeline) (see [0017]) comprises:

composition ingredient determination means (Fig. 15A subroutine 1510)

(see Wang Ho: [0094]) for determining composition ingredient information (e.g. component database 910) (see [0065] and [0094]) for each process of medicines developed according to the main ingredient information (e.g. structure) (see Wang Ho: [0065] for descriptions of their chemical composition; [0094] for partition structure into component groups);

transmission means (Fig. 5 mass screening 530) (see Wang Ho: [0017] for screening an entire database of known compounds. This database is the same as Boyd's database connected to the network, as note above. Both databases provide information for an external company) for transmitting the composition ingredient information (e.g. component database 910) (see Wang Ho: [0065] and [0094]) for each process of medicines developed and obtained by the composition ingredient determination means (Fig. 15A subroutine 1510) (see Wang Ho: [0094]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized composition ingredient determination and transmission means as taught by Wang Ho to the system of Boyd because the ability to easily cross-reference components by chemical composition, which facilitates user-

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directed structure generation, and thus is another powerful aid to the development of new drugs (see Wang Ho: [0062]).

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## Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hoffman et al. (U.S. Pub. No. 2003/0069799) teaches a system, method and computer program product for a chemical supply chain management.

Kataria et al. (U.S. Pub. No. 2005/0197786) teaches a system and method for managing the development and manufacturing of a pharmaceutical drug.

Desouza (PCT Pub. No. WO01/65441) teaches a system and method for the automated selection of formulation components by specifying product characteristics serve customers within market segments that use selected components as raw materials for manufacture of specialty products.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tejal J. Gami whose telephone number is (571) 270-1035. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chanh Nguyen can be reached on (571) 272-7772. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tejal Gami Examiner Art Unit 2193

TJG TJG

CHANH D. NGUYEN SUPERVISORY PATENT EXAMINER